IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
NEWARK DIVISION

BARBARA BOYD, Plaintiff, v. ASTRAZENECA PHARMACEUTICALS LP; and ASTRAZENECA LP, Defendants.	)	Civil Action No. 2:16-cv-08121 **ANSWER OF ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP TO PLAINTIFF'S COMPLAINT** **DEMAND FOR JURY TRIAL**

ANSWER OF ASTRAZENECA PHARMACEUTICALS LP AND ASTRAZENECA LP TO PLAINTIFF'S COMPLAINT

Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP ("AstraZeneca"), by counsel, answer and respond to Plaintiff's Complaint ("Complaint") as follows:

NATURE OF THE ACTION

1. AstraZeneca admits that Plaintiff has attempted to assert causes of action for personal injuries and economic damages, but denies the remaining allegations set forth in Paragraph 1.

2. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca further admits that Nexium® is a prescription medication approved by the FDA, accompanied by an FDA-approved package insert, and is subject to various reporting requirements. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® package insert were

approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 2.

3. AstraZeneca denies the allegations set forth in Paragraph 3.

4. AstraZeneca denies the allegations set forth in Paragraph 4.

PARTIES

Plaintiff, Her use of Nexium and Resulting Harm

5. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 5 and, therefore, denies same.

6. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 6 and, therefore, denies same.

7. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 7 and, therefore, denies same.

8. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 8 regarding Plaintiff and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 8.

9. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 9 and, therefore, denies same.

10. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 10 and, therefore, denies same.

Defendants

AstraZeneca Pharmaceuticals LP

11. AstraZeneca admits that AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of Delaware with its principal place of business in Delaware. AstraZeneca denies the remaining allegations set forth in Paragraph 11.

12. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 12 as stated.

13. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 13 as stated.

14. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 14 as stated.

15. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 15 as stated.

16. AstraZeneca admits that AstraZeneca Pharmaceuticals LP is the holder of New Drug Application Numbers 021153, 021957, and 022101, but denies the remaining allegations set forth in Paragraph 16, including all subparts, as stated.

AstraZeneca LP

17. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 17 as stated.

18. AstraZeneca admits AstraZeneca LP is a limited partnership organized under the laws of Delaware with its principal place of business in Delaware. AstraZeneca denies the remaining allegations set forth in Paragraph 18.

19. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 19 as stated.

20. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 20 as stated.

21. AstraZeneca admits AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 21 as stated.

AstraZeneca Pharmaceuticals LP & AstraZeneca LP's Unity of Interest[1]

22. Because there are no legal or factual allegations contained in Paragraph 22, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 22.

23. To the extent Paragraph 23 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca admits that the general partnership of AstraZeneca Pharmaceuticals LP and AstraZeneca LP speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 23 as stated.

24. To the extent Paragraph 24 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca admits that the general partnership of AstraZeneca Pharmaceuticals LP and AstraZeneca LP speaks for itself. AstraZeneca otherwise denies any remaining allegations set forth in Paragraph 24 as stated.

JURISDICTION AND VENUE

25. AstraZeneca admits that this Court has subject matter jurisdiction. AstraZeneca denies that Plaintiff is entitled to the relief sought.

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[1] AstraZeneca has utilized the headings contained in Plaintiff's Complaint. To the extent Plaintiff's headings set forth legal or factual allegations that require AstraZeneca to respond, AstraZeneca denies the allegations set forth therein.

26. To the extent Paragraph 26 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 26.

27. To the extent Paragraph 27 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 27.

28. To the extent Paragraph 28, including all subparts, states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 28, including all subparts.

29. To the extent Paragraph 29 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States, but denies the remaining allegations set forth in Paragraph 29.

30. AstraZeneca denies the allegations set forth in Paragraph 30.

31. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 31 as stated.

32. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 32 as stated.

33. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 33 as stated.

34. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 34 as stated.

35. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca is without knowledge or information sufficient to form a belief as to the remaining allegations set forth in Paragraph 35 and, therefore, denies same.

36. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca denies the remaining allegations set forth in Paragraph 36.

FACTUAL BACKGROUND

Proton Pump Inhibitors Generally

37. AstraZeneca admits that Nexium® is an FDA-approved prescription medication and that the conditions for which it is indicated are set forth in the product label. AstraZeneca denies the remaining allegations set forth in Paragraph 37, including all subparts, as stated.

38. AstraZeneca denies the allegations set forth in Paragraph 38.

39. AstraZeneca admits that AstraZeneca entities market and sell Nexium® with National Drug Code numbers 0186-5020, 0186-5040, and 0186-4040. AstraZeneca denies the remaining allegations set forth in Paragraph 39 as stated.

40. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in the first sentence of Paragraph 40, including the undefined, subjective terms "largest-selling," "world market," and "overall" and, therefore, denies same. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 40 and, therefore, denies same.

41. AstraZeneca admits that Nexium® is a prescription proton pump inhibitor medication approved by the FDA and that its clinical pharmacology is set forth in the product label. AstraZeneca denies the remaining allegations set forth in Paragraph 41 as stated.

Dangers Associated with PPIs

42. AstraZeneca denies the allegations set forth in Paragraph 42.

43. AstraZeneca admits that AstraZeneca entities market and sell Nexium® in the United States. AstraZeneca further admits that Nexium® is a prescription medication approved by the FDA, accompanied by an FDA-approved package insert, and is subject to various reporting requirements. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® package insert were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 43, including all subparts.

44. AstraZeneca denies the allegations set forth in Paragraph 44.

Increased Risk of Acute Interstitial Nephritis (AIN) with PPIs

45. To the extent Paragraph 44 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 45 as stated.

46. AstraZeneca denies the allegations set forth in Paragraph 46 as stated.

47. AstraZeneca denies the allegations set forth in Paragraph 47 as stated.

48. AstraZeneca denies the allegations set forth in Paragraph 48 as stated.

49. AstraZeneca admits that Nexium® is a prescription medication approved by the FDA and accompanied by an FDA-approved package insert, which speaks for itself. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® package insert were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its

obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 49 as stated.

50. AstraZeneca denies the allegations set forth in Paragraph 50 as stated.

51. AstraZeneca denies the allegations set forth in Paragraph 51.

52. To the extent Paragraph 52 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 52 as stated.

Association between Chronic Kidney Disease (CKD) and PPIs

53. To the extent Paragraph 53 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 53 as stated.

54. To the extent Paragraph 54 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 54 as stated.

55. To the extent Paragraph 55 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 55 as stated.

56. To the extent Paragraph 56 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 56 as stated.

57. AstraZeneca denies the allegations set forth in Paragraph 57 as stated.

58. AstraZeneca denies the allegations set forth in Paragraph 58 as stated.

59. To the extent Paragraph 59 calls for a medical conclusion, any such response by AstraZeneca would be premature and inappropriate. To the extent AstraZeneca is required to respond, AstraZeneca denies the allegations set forth in Paragraph 59 as stated.

60. AstraZeneca denies the allegations set forth in Paragraph 60 as stated.

61. AstraZeneca admits that Nexium® is a prescription medication approved by the FDA and accompanied by an FDA-approved package insert, which speaks for itself. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® package insert were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 61.

Acute Kidney Injury (AKI) Dangers Associated with PPIs

62. AstraZeneca denies the allegations set forth in Paragraph 62 as stated.

63. AstraZeneca denies the allegations set forth in Paragraph 63 as stated.

64. AstraZeneca denies the allegations set forth in Paragraph 64 as stated.

65. AstraZeneca admits that Nexium® is a prescription medication approved by the FDA and accompanied by an FDA-approved package insert, which speaks for itself. AstraZeneca further admits that any and all contraindications, warnings, precautions, adverse reactions and/or other information in the Nexium® package insert were approved by the FDA and transmitted to prescribing physicians and/or healthcare providers. AstraZeneca fulfilled its obligation under the law to provide adequate warnings and instructions. AstraZeneca denies the remaining allegations set forth in Paragraph 65.

Availability of Safer Alternatives to PPIs

66. To the extent Paragraph 66 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 66.

67. To the extent Paragraph 67 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 67, including all subparts.

68. To the extent Paragraph 68 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 68.

69. AstraZeneca denies the allegations set forth in Paragraph 69.

Allegations Common to All Causes of Action

70. AstraZeneca denies the allegations set forth in Paragraph 70.

71. AstraZeneca denies the allegations set forth in Paragraph 71.

72. AstraZeneca denies the allegations set forth in Paragraph 72.

TOLLING OF THE STATUTE OF LIMITATIONS

73. AstraZeneca denies the allegations set forth in Paragraph 73.

74. To the extent Paragraph 74 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 74.

CASE-SPECIFIC INFORMATION

75. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 75 regarding Plaintiff's treatment and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 75.

76. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 76 regarding Plaintiff's treatment and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 76.

77. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 77 regarding Plaintiff and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 77.

78. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 78 regarding Plaintiff's treatment and, therefore, denies same. AstraZeneca denies the remaining allegations set forth in Paragraph 78.

79. AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 79 and, therefore, denies same.

COUNT I
NEGLIGENCE

80. In response to the allegations contained in Paragraph 80, AstraZeneca re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

81. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose

laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 81 as stated and denies it breached any duty.

82. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 82.

83. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 83.

84. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 84.

85. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 85.

86. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 86.

87. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 87.

88. Plaintiff's negligence cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 88.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" paragraph immediately following Paragraph 88. AstraZeneca also requests a trial by jury.

COUNT II
BREACH OF EXPRESS WARRANTY

89. In response to the allegations contained in Paragraph 89, AstraZeneca re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

90. To the extent Paragraph 90 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 90.

91. To the extent Paragraph 91 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 91.

92. To the extent Paragraph 92 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond, as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 92 and, therefore, denies same.

93. AstraZeneca denies the allegations set forth in Paragraph 93.

94. AstraZeneca denies the allegations set forth in Paragraph 94.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" paragraph immediately following Paragraph 94. AstraZeneca also requests a trial by jury.

COUNT III
BREACH OF IMPLIED WARRANTY

95. In response to the allegations contained in Paragraph 95, AstraZeneca re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

96. Plaintiff's breach of implied warranty cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United

States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 96.

97. Plaintiff's breach of implied warranty cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, insofar as Paragraph 92 states legal conclusions, no response is required. To the extent AstraZeneca may be required to respond as to the actions of others, AstraZeneca is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 97 and, therefore, denies same.

98. Plaintiff's breach of implied warranty cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 98.

99. Plaintiff's breach of implied warranty cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 99.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" paragraph immediately following Paragraph 99. AstraZeneca also requests a trial by jury.

COUNT IV
FRAUD

100. In response to the allegations contained in Paragraph 100, AstraZeneca re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

101. Plaintiff's fraud cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 101.

102. Plaintiff's fraud cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 102.

103. Plaintiff's fraud cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 103.

104. Plaintiff's fraud cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose

laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 104.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" paragraph immediately following Paragraph 104. AstraZeneca also requests a trial by jury.

COUNT V
NEGLIGENT MISREPRESENTATION

105. In response to the allegations contained in Paragraph 105, AstraZeneca re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

106. Plaintiff's negligent misrepresentation cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 106.

107. Plaintiff's negligent misrepresentation cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 107.

108. Plaintiff's negligent misrepresentation cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the

United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 108.

109. Plaintiff's negligent misrepresentation cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 109.

110. Plaintiff's negligent misrepresentation cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 110.

111. Plaintiff's negligent misrepresentation cause of action is subsumed by the relevant portions of the Product Liability Act, N.J.S.A. 2A:58C-1 *et seq.* and may be subsumed by the relevant portions of the Product Liability Act of any other State or Commonwealth of the United States whose laws might be deemed controlling in this case. To the extent AstraZeneca may be required to respond, AstraZeneca denies the allegations set forth in Paragraph 111.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" paragraph immediately following Paragraph 111. AstraZeneca also requests a trial by jury.

PUNITIVE DAMAGES ALLEGATIONS

112. In response to the allegations contained in Paragraph 112, AstraZeneca re-alleges and incorporates by reference each and every response set forth above as if set forth herein and in full.

113. AstraZeneca denies the allegations set forth in Paragraph 113.

114. AstraZeneca denies the allegations set forth in Paragraph 114.

115. AstraZeneca denies the allegations set forth in Paragraph 115.

116. AstraZeneca denies the allegations set forth in Paragraph 116.

AstraZeneca denies that Plaintiff is entitled to any of the relief requested in the "WHEREFORE" paragraph immediately following Paragraph 116. AstraZeneca also requests a trial by jury.

RELIEF REQUESTED

In response to the Paragraph entitled "Relief Requested," AstraZeneca denies that Plaintiff is entitled to any of the relief requested.

JURY TRIAL DEMAND

AstraZeneca hereby demands a jury trial on all claims so triable in this action.

AFFIRMATIVE DEFENSES

Discovery and investigation may reveal that one or more of the following affirmative defenses should be available to AstraZeneca in this matter. AstraZeneca accordingly preserves the right to assert those separate and affirmative defenses. Upon completion of discovery, if facts warrant, AstraZeneca may withdraw any of the affirmative defenses as may be appropriate. AstraZeneca further reserves the right to amend this answer to assert additional defenses and other claims as discovery proceeds.

By alleging the matters set forth below, AstraZeneca does not admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters. If necessary and/or in the alternative, AstraZeneca raises the following defenses available in the State of New Jersey and any State or Commonwealth of the United States whose laws might be deemed controlling in this case, but reserves the right to amend its Answer to raise any additional defenses which it may have against Plaintiff's claims:

FIRST DEFENSE

Plaintiff's claims and causes of action are barred by the applicable statute of limitations, and/or repose, and/or may be otherwise untimely.

SECOND DEFENSE

Plaintiff fails to state a claim upon which relief can be granted as required by Federal Rule of Civil Procedure 12(b).

THIRD DEFENSE

This Court lacks personal jurisdiction over AstraZeneca, and thus the Complaint should be dismissed under Rule 12(b)(2) of the Federal Rules of Civil Procedure.

FOURTH DEFENSE

Plaintiff fails to plead her claims against AstraZeneca with sufficient particularity as required by Federal Rule of Civil Procedure 9(b).

FIFTH DEFENSE

Nexium® is a prescription pharmaceutical which was available only upon prescription of a licensed physician. Any warnings that AstraZeneca gave were transmitted to prescribing physicians and/or healthcare providers. Under applicable state law, AstraZeneca fulfilled its

obligation to provide adequate warnings and instructions. Plaintiff's claims are therefore barred pursuant to the learned intermediary doctrine.

SIXTH DEFENSE

If Plaintiff sustained the injuries or damages as alleged, said injuries and expenses were directly and proximately caused by the acts and omissions (wrongful or otherwise),negligence, sole fault, misuse, abuse, modification, alteration, omission, or fault of one or more parties other than AstraZeneca over whom AstraZeneca had no supervision or control and for whose actions and omissions AstraZeneca has no legal responsibility. AstraZeneca is not liable for negligence and violated no duty that may have been owed to Plaintiff.

SEVENTH DEFENSE

AstraZeneca's activities conformed to all state and federal statutes, regulations, and industry standards based upon the state of the knowledge that existed at the time.

EIGHTH DEFENSE

Plaintiff's recovery is barred and/or should be reduced under the applicable law because of Plaintiff's contributory negligence or fault, comparative negligence or fault, culpable conduct, intentional acts, assumption of risk, and/or want of care.

NINTH DEFENSE

Plaintiff's injuries and damages, if any, resulted from an intervening or superseding cause or causes and any act or omission on the part of AstraZeneca was not the proximate and/or competent producing cause of such alleged injuries or damages.

TENTH DEFENSE

AstraZeneca did not sell or distribute products directly to Plaintiff. Plaintiff's claims are, therefore, barred by lack of privity between Plaintiff and AstraZeneca.

ELEVENTH DEFENSE

Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards and techniques utilized with respect to the design, manufacture, marketing, distribution, and sale of Nexium®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature conformed to the applicable state of the art. The product in question, including its FDA-approved labeling, complied with the state of scientific and medical knowledge available to AstraZeneca at the time of its manufacture, distribution, and sale.

TWELFTH DEFENSE

With respect to each and every purported cause of action, the acts of AstraZeneca were at all times done in good faith and without malice.

THIRTEENTH DEFENSE

Plaintiff's claims are barred in whole or in part under comment *k* to Section 402A of the Restatement (Second) of Torts.

FOURTEENTH DEFENSE

Plaintiff's claims are barred in whole or in part because AstraZeneca provided legally adequate "directions or warnings" as to the use of the product at issue and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment *j* to Section 402A of the Restatement (Second) of Torts.

FIFTEENTH DEFENSE

Plaintiff's claims are barred as a matter of law pursuant to Sections 2, 4, 6(c), 6(d) and comment *f* to Section 6, of the Restatement (Third) of Torts: Products Liability.

SIXTEENTH DEFENSE

With respect to each and every cause of action, Plaintiff cannot state claims founded in strict liability because, among other things, comments *j* and *k* to Section 402A of the Restatement (Second) of Torts relegate Plaintiff's claims to a negligence cause of action.

SEVENTEENTH DEFENSE

Nexium® complied with all applicable state and federal statutes regarding the product in question, including product safety regulations promulgated by the FDA and contained in Chapter 21 of the Code of Federal Regulations as well as the industry standards based upon the state of knowledge existing at the relevant time alleged in by the Complaint. The product at issue was reasonably fit, suitable, and safe for its respective intended uses, demonstrating that due care was exercised with respect to the design, manufacture, testing, marketing, distribution, and sale of Nexium®. In the event that Plaintiff's claims are not barred, AstraZeneca is entitled to a presumption that the product in question is free from any defect or defective condition as the plans or design for the product or the methods and techniques of manufacturing, inspecting, and testing the product were in conformity with government standards established for the drug industry that were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting, and testing the product were adopted.

EIGHTEENTH DEFENSE

Plaintiff's claims are barred because Nexium® was neither defective nor unreasonably dangerous in its design, manufacture, distribution, or marketing, and was reasonably safe and reasonably fit for its intended use, thereby barring Plaintiff's recovery.

NINETEENTH DEFENSE

If Plaintiff sustained the injuries or damages as alleged, said injuries or damages were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of the prescription drug Nexium® thereby barring Plaintiff's recovery against AstraZeneca.

TWENTIETH DEFENSE

Plaintiff's claims are barred to the extent Plaintiff knew the condition of Nexium®, appreciated the risks of injury flowing from Nexium® use, and nevertheless proceeded to use Nexium® without regard to the danger of such risks. As a result, Plaintiff gave informed consent and/or assumed the risk of injury of which he now complains.

The extent of any risk associated with the use of the product at issue, the existence of which is not admitted, was, at the time of the distribution of said product by AstraZeneca, unknown and could not have been known by the use of ordinary care.

TWENTY-FIRST DEFENSE

The public interest in the benefit and availability of the product which is the subject matter of this action precludes liability, if any, resulting from any activities undertaken by AstraZeneca, which were unavoidable given the state of human knowledge at the time those activities were undertaken. With respect to Plaintiff's claims, if it is determined there exists a risk inherent in the subject product, then such risk, if any, is outweighed by the benefit of the product.

TWENTY-SECOND DEFENSE

Plaintiff's failure to warn claim is barred given that AstraZeneca had no duty to warn of risks of which they neither knew nor should have known at the time the Nexium® was designed, distributed, and manufactured.

TWENTY-THIRD DEFENSE

Plaintiff's injuries and damages, if any, were the result of an idiosyncratic reaction that AstraZeneca could not have reasonably foreseen, thereby barring Plaintiff's recovery.

TWENTY-FOURTH DEFENSE

Plaintiff's claims are barred because the alleged injuries and damages, if any, were caused by medical conditions, disease, illness, or processes (whether pre-existing or contemporaneous) unrelated to any conduct of AstraZeneca or condition of the product, Nexium®, thereby barring Plaintiff's recovery.

TWENTY-FIFTH DEFENSE

Plaintiff has not sustained an ascertainable loss of property or money, nor any actual injury or damages.

TWENTY-SIXTH DEFENSE

Plaintiff's claims are barred under the doctrine of economic loss.

TWENTY-SEVENTH DEFENSE

Plaintiff failed to mitigate her damages.

TWENTY-EIGHTH DEFENSE

Plaintiff's claims for breach of warranty are barred because Plaintiff failed to give a timely notice of any alleged breach of warranty pursuant to the applicable state's Uniform Commercial Code.

TWENTY-NINTH DEFENSE

AstraZeneca's advertisements and labeling with respect to the product which is the subject of this action were not false or misleading and, therefore, constitute protected

commercial speech under the applicable provisions of the Unites States Constitution and this State.

THIRTIETH DEFENSE

AstraZeneca is entitled to protection under the *Noerr-Pennington* doctrine, which provides that parties who exercise their First Amendment right to communicate and/or petition the government are immune from liability premised on any such efforts.

THIRTY-FIRST DEFENSE

AstraZeneca denies any liability, but if AstraZeneca is ultimately found liable to Plaintiff, then it shall only be liable for their equitable share of Plaintiff's recovery since any liability which would be found against AstraZeneca will be insufficient to impose joint liability.

THIRTY-SECOND DEFENSE

If Plaintiff recovers from AstraZeneca, AstraZeneca is entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause the Plaintiff's alleged damages.

THIRTY-THIRD DEFENSE

Any verdict or judgment rendered against AstraZeneca must be reduced by those amounts that have, or will, with reasonable certainty, replace or indemnify Plaintiff in whole or in part, for any past or future claimed economic loss from any collateral source, such as insurance, social security, worker's compensation, or employee benefit programs.

THIRTY-FOURTH DEFENSE

Plaintiff's damages, if any, are barred or reduced by the doctrine of avoidable consequences.

THIRTY-FIFTH DEFENSE

To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, AstraZeneca's liability, if any, should be precluded or reduced accordingly.

THIRTY-SIXTH DEFENSE

To the extent Plaintiff seeks recovery of punitive or exemplary damages against AstraZeneca, unless AstraZeneca's liability for punitive damages and the appropriate amount of punitive damages is required to be established by clear and convincing evidence, any award of punitive damages would violate AstraZeneca's constitutional rights, including but not limited to those under the due process clauses in the Fifth and Fourteenth Amendments to the United States Constitution and any applicable state constitution, and would be improper under the common law, public policies, applicable statutes and court rules of the applicable states to these amendments and the excessive fines clause in the Eighth Amendment to the Constitution of the United States and double jeopardy clause in the Fifth Amendment to the Constitution of the United States.

THIRTY-SEVENTH DEFENSE

To the extent Plaintiff seeks recovery of punitive or exemplary damages against AstraZeneca, any such claim of Plaintiff for punitive damages against AstraZeneca cannot be maintained because there was no act or omission by AstraZeneca that was oppressive, fraudulent, or malicious. Additionally, any award of punitive damages under the applicable law would be unlawful and unauthorized, and would be void for vagueness, both facially and as applied, as a result of, among other deficiencies, the absence of adequate notice of what conduct is subject to punishment; the absence of adequate notice of what punishment may be imposed;

and the absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount of punitive damages that a jury may impose, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the applicable state constitution, and the common law and public policies of that state.

THIRTY-EIGHTH DEFENSE

To the extent Plaintiff seeks recovery of punitive damages against AstraZeneca, any such claim of Plaintiff for punitive damages against AstraZeneca cannot be maintained because any award of punitive damages under the applicable law would be by a jury that (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award, (2) is not adequately instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment, (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including residence, wealth, and corporate status of AstraZeneca, (4) is permitted to award punitive damages under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible, (5) is permitted to award punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, if any, to Plaintiff, (6) is permitted to award punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any, (7) is not subject to adequate, independent, de novo trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards and in conformity with the United States

Constitution as amended or any applicable State constitution. Any such verdict would violate AstraZeneca's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the due process and equal protection provisions of any applicable state constitution, and would be improper under the common law and public policies of that state.

Additionally, punitive damages may not be recovered to the extent such damages are: (1) imposed where state law is impermissibly vague, imprecise, or inconsistent, (2) subject to no predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, or (3) imposed on the basis of anything other than AstraZeneca's conduct within the State where Plaintiff resides, or in any other way subjecting AstraZeneca to impermissible multiple punishment for the same alleged wrong.

THIRTY-NINTH DEFENSE

To the extent Plaintiff seeks recovery of punitive or exemplary damages against AstraZeneca, any award of punitive damages based on anything other than AstraZeneca's conduct in connection with the design, manufacture, and sale of Nexium® would violate the due process clause of the Fourteenth Amendment of the United States Constitution and the due process provisions of the applicable state constitution, and would be improper under the common law and public policies of that state, because any other judgment for punitive damages in this case cannot protect AstraZeneca against impermissible punishment for the same wrong and against punishment for extraterritorial conduct, including conduct that is lawful in states other than the applicable state. In addition, any award would violate principles of comity under the laws of that state.

FORTIETH DEFENSE

AstraZeneca incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damage awards as applied to the state and federal courts under the Due Process Clause of the Fourteenth Amendment to the United States Constitution, including but not limited to standards set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and their progeny.

FORTY-FIRST DEFENSE

AstraZeneca assert the provisions of all applicable statutory caps on damages of any sort, including compensatory, punitive, non-economic or exemplary damages, under applicable regulations and/or laws.

FORTY-SECOND DEFENSE

There was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by Plaintiff or reduced the alleged risk, without substantially impairing the usefulness, safety, efficacy, or intended purpose of Nexium®, thereby barring Plaintiff's recovery.

FORTY-THIRD DEFENSE

Plaintiff's purported allegations of misrepresentation fail to state a claim for which relief may be granted. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

FORTY-FOURTH DEFENSE

The AstraZeneca product at issue has been formulated, designed, tested, manufactured, processed, distributed, and labeled in accordance with the provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.§ 301, *et seq.*, and regulations promulgated thereunder. Therefore, Plaintiff's claims predicated on state tort law and alleging that Nexium® is unsafe are barred, in whole or in part, by the doctrine of federal preemption and the Supremacy Clause of the United States Constitution, Article IV, clause 2.

FORTY-FIFTH DEFENSE

To the extent that Plaintiff asserts claims based on AstraZeneca's adherence to and compliance with applicable state laws, regulations, and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

FORTY-SIXTH DEFENSE

Plaintiff's claims are barred and/or this Court should defer this matter, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged under the law with regulating drugs, including the product at issue, and is specifically charged with determining the content of warnings and labeling for drugs.

FORTY-SEVENTH DEFENSE

Plaintiff's claims may be barred by failure to join an indispensable party or real party in interest necessary for the just adjudication of this matter.

FORTY-EIGHTH DEFENSE

AstraZeneca is entitled to the protections and limitations afforded under the law of Plaintiff's state of residence and any other state whose law is deemed to apply in this case.

FORTY-NINTH DEFENSE

The Complaint fails to give AstraZeneca reasonable notice of facts sufficient to complete a choice of law analysis. Pending a determination of applicable law, AstraZeneca pled all applicable affirmative defenses under New Jersey law, and reserves the right to assert further or additional affirmative defenses if it is determined that such defenses exist under applicable state law(s).

FIFTIETH DEFENSE

No act or omission by AstraZeneca was the proximate cause, contributing cause, or otherwise a cause of any damages alleged by Plaintiff. The negligence of other persons or entities who are not parties to this suit was the sole proximate cause of, or a contributing cause to, the damages alleged in the Complaint. AstraZeneca anticipate that more specific information regarding the identity and potential liability of these non-parties will be developed during discovery.

To the extent Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate AstraZeneca's rights under the United States Constitution.

FIFTY-FIRST DEFENSE

Plaintiff received all or substantially all of the benefit from the subject product that Plaintiff hoped and intended to receive, and to that extent, any damages and/or restitution that Plaintiff might be entitled to recover from AstraZeneca must be correspondingly barred or reduced.

FIFTY-SECOND DEFENSE

Plaintiff's claims are barred by laches, waiver, accord and satisfaction, payment, release, res judicata, estoppel, spoliation of evidence, and/or the applicability of arbitration and award.

FIFTY-THIRD DEFENSE

This case may be subject to dismissal or stay on the grounds of *forum non conveniens*.

FIFTY-FOURTH DEFENSE

Plaintiff is barred from pursuing her claims and causes of action in the District of New Jersey because venue is improper, and each claim should be dismissed under Rule 12(b)(3) of the Federal Rules of Civil Procedure, or in the alternative, transferred to the proper venue.

FIFTY-FIFTH DEFENSE

Plaintiff is not entitled to recover attorneys' fees under any applicable law.

McCARTER & ENGLISH, LLP
Attorneys for Defendants,
AstraZeneca Pharmaceuticals LP and
AstraZeneca LP

By: */s/ Debra M. Perry*
Debra M. Perry
A Member of the Firm

Dated: February 28, 2017